

CERTIFICATE OF ANALYSIS

(Certificate No. KMA078017-02)

Release Date: 19/07/2025

Re-test Date: 18/07/2028

Albuterol EP Impurity G

Identification

Chemical Name :

2-[benzyl(tert-butyl)amino]-1-[4-hydroxy-3-(hydroxymethyl)phenyl]ethan-1-one (as per EP)

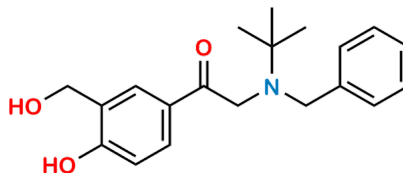
Alt. Name : Salbutamol BP Impurity G ; N-Benzyl
Salbutamone HCl ; Benzylsalbutamon

CAT No. : KMA078017

CAS No. : 64092-10-0

Molecular Formula : C₂₀H₂₅NO₃

Molecular Weight : 327.4



Analytical Information

Batch No. : A078017-102-134

Solubility : Acetonitrile

Description : Light Yellow Thick Syrup

Mass : Confirm

HPLC Purity : 99.31 %

IR : Confirm

Weight Loss By TGA : 0.64 %

¹H NMR : Confirm

% Potency : 98.67 %

¹³C NMR : Confirm

Additional Information

Long Term Storage : Store at 2-8 deg. C for long term storage

Shipping Condition : Product is stable to be Shipped at Room Temperature

% Potency = [100 - 0.64(Weight Loss By TGA)] x [99.31(HPLC Purity)]/100 = 98.67 %

*As per client request chemical name change as per EP monograph

Recommendation : Released

	Department	Name	Signature	Date
Prepared By	Analytical	Jignesh Patel		22/08/2025
Reviewed & Approved By	Quality Control	Jatin Patel		22/08/2025

Attachments : COA, HPLC, MASS, ¹HNMR, ¹³CNMR, IR and TGA